REF: 208.06.25.01

SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)

Instructions for Use

CE

For Professional Use Only
For in vitro diagnostic use only
Store at 2℃ -30℃

CONTENT

1. INTENDED USE

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection: asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The genome of coronavirus encodes spike protein, envelope protein, membrane protein and nucleocapsid. In the process of viral assembly, N protein binds to viral RNA and leads to the formation of spiral nucleocapsid. N protein is a highly immunogenic phosphoprotein, which is related to viral genome replication and cell signalling. Because of the conserved sequence of N protein, detection of SARS-CoV-2 N protein is of great clinical significance.

This rapid kit is used for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen (hereinafter referred to as SARS-CoV-2 N-antigen) in anterior nasal swab samples.

2. TEST PRINCIPLE

The test analyte in the sample will form a complex with the fluorescent microsphere-labelled antibody on the conjugate pad under chromatography, and the complex will continue to be chromatographed on the nitrocellulose membrane until reaching test line (T line), then captured by the test line antibody. The unbound microspheres are chromatographed to the quality control line (C line) and captured by the antibody on the quality control line. The fluorescence signal intensity can be detected and analyzed by BOH-180 Fluorescent Immunoassay Analyzer. The analyzer converts the fluorescence signals into corresponding concentrations.

3. KIT COMPONENTS

1 Instructions for Use
25 Test Cassettes
25 Swabs
25 Extraction Buffer
25 Extraction Tubes with Caps

4. WARNINGS AND PRECAUTIONS

4.1. For in vitro diagnostic use only. Do not use after expiration date.

4.2. Samples should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and are advised to take other appropriate safety precautions to avoid or reduce the risk of infection.

4.3. This test should be performed at 15-30℃. The test and samples must be brought to room temperature before testing.

4.4. Follow the Instructions for Use carefully. The accuracy of the assay results cannot be guaranteed if there is any deviation from the instructions for Use.

4.5. Operators must handle the potentially contaminated materials safely according to local requirements.

4.6. Use a new clean disposable extraction tube for each sample to avoid cross contamination.

4.7. Although the test kit uses detergents in the extraction buffer which neutralize SARS-CoV-2,

dispose of all samples and materials as if they were infectious waste in a biohazard waste container.

4.8. Once the test cassette is removed from the pouch, perform the test as soon as possible to avoid being humidified. The test cassette is sensitive to humidity as well as to heat.

4.9. Do not use the test cassette if the pouch is damaged or if the seal is broken.

4.10. The test cassette cannot be reused.

5. STORAGE CONDITIONS AND SHELF LIFE

The test can be stored at 2℃-30℃ for 12 months from the date of manufacture. The test cassette inside the foil bag shall be used within 1 hour after opening.

6. APPLICABLE INSTRUMENTS

BOH-180 Fluorescent Immunoassay Analyzer produced by Biohit Healthcare (Hefei) Co., Ltd.

7. SAMPLE REQUIREMENTS

7.1 Applicable to anterior nasal swab samples.

7.2. It is recommended that the samples are tested at the time of sample collection.

7.3. If not tested immediately, the anterior nasal swab samples should be stored in a dry and clean tube tightly sealed. The samples can be stored at 2-8℃ for up to 24 hours.

7.4. For long-term storage, the samples should be stored at -20℃. Avoid repeated freezing and thawing of samples.

8. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Quality Control

9. COLLECTION OF SWAB SAMPLES

9.1. The test can be performed according to the standard anterior nasal swab sample collection procedure.

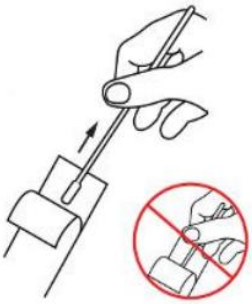
9.2. Anterior nasal swab sample collection:

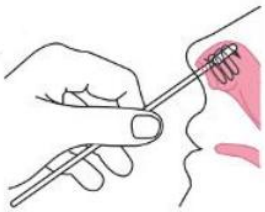
(1) Remove the swab from the pouch and hold with the handle only. Do not touch the swab tip.

(2) Gently insert the swab up to 1/2 to 3/4 of an inch into the nostril of the patient. Roll the swab around the inside wall of nostril at least 4 times.

(3) Repeat swab step for the other nostril with the same swab to ensure adequate sample is collected.

9.3. It is recommended that the sample be tested at the time of sample collection.





10. TEST PROCEDURE

Step 1: Break the tip of the single use vial with extraction buffer.

Step 2: Pour all the extraction buffer inside into the extraction tube.

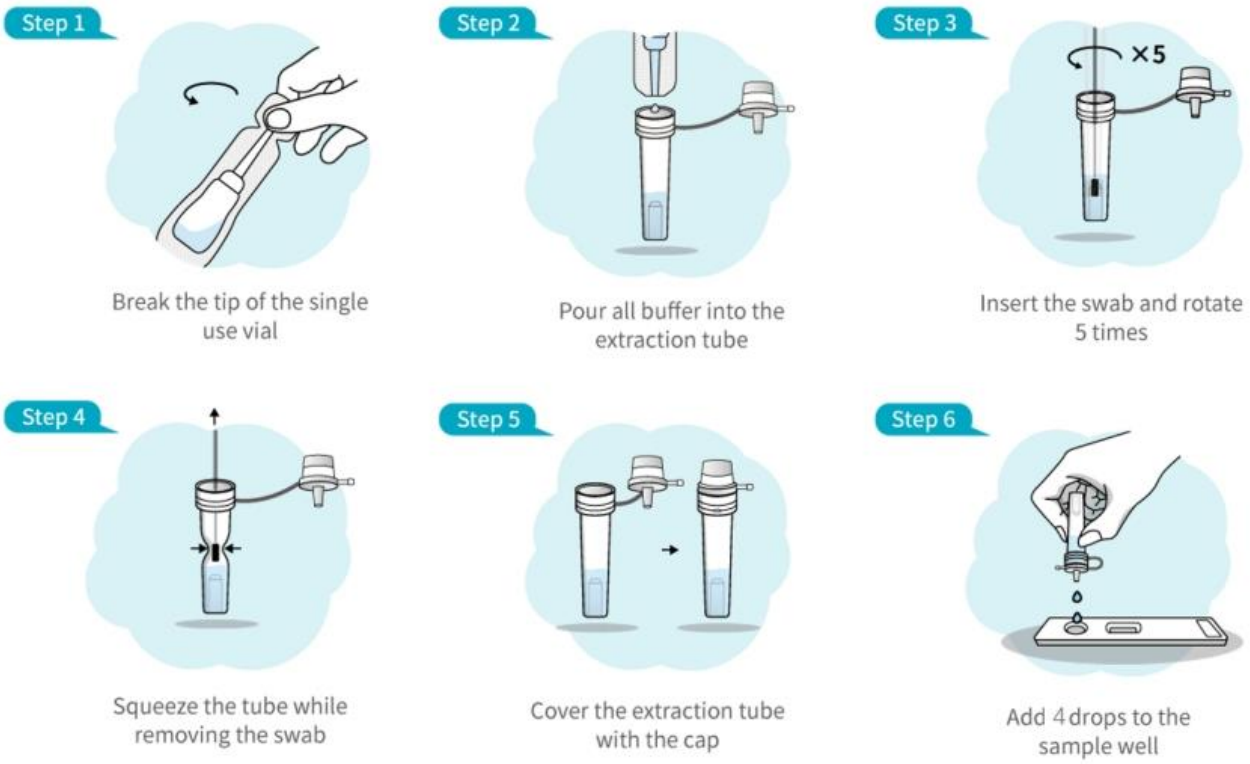
Step 3: Insert the swab into the extraction tube. Rotate the swab 5 times and squeeze the sides of the extraction tube to mix the sample in the buffer.

Step 4: Remove the swab while squeezing the sides of the extraction tube to extract the liquid from the swab as much as possible. Discard the swab.

Step 5: Place the filter cap on the extraction tube and press firmly so that the cap sits tightly in the extraction tube.

Step 6: Place the test cassette on a flat surface. Apply 4 drops of extracted sample to the sample well of the test cassette. Dispense the sample at 90 degree angle to avoid bubbles.

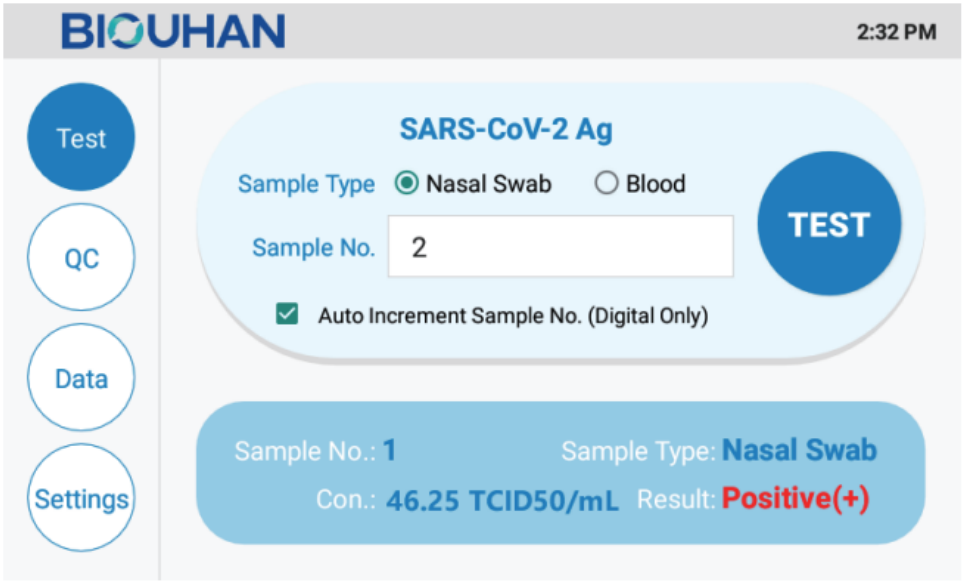
Step 7: After 15 minutes, insert the test cassette into the cassette slot of BOH-180. Press Test, and BOH-180 will automatically run test and generate test results.



11. INTERPRETATION OF THE RESULTS

11.1.The analyzer converts the fluorescence signals into corresponding concentrations.

Concentration higher than or equal to 12.69 $TCID_{50}$/mL indicates SARS-CoV-2 antigen positive while concentration lower than 12.69 $TCID_{50}$/mL indicates SARS-CoV-2 antigen negative. If the chromatography is not successful and the analyzer gives "Result: Failure", it indicates that the test fails and the sample needs to be retested with a new test cassette.



11.2. Due to the complex structure of bioactive substances in samples and the difference of antigen antibody specificity, the possibility of false positive results cannot be completely ruled out when using this kit. If the test results are inconsistent with the clinical indications, other appropriate test methods should be used for confirmation.

12. LIMITATION OF THE PROCEDURES

12.1. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage or repeated freezing and thawing of the sample may affect the test result.

12.2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

12.3. The performance of SARS-CoV-2 Antigen Rapid Test was evaluated using the procedures provided in the product insert only. Modifications to these procedures may alter the performance of the test.

12.4. False negative results may occur if swabs are stored in their paper sheath after specimen collection.

12.5. Positive test results do not rule out co-infections with other pathogens.

12.6. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

12.7. Swab sample after heat inactivation may affect the accuracy of the detection and may lead to erroneous results.

13. PERFORMANCE CHARACTERISTICS

Limit of Blank

The LoB is confirmed as 9.36 $TCID_{50}$/mL.

Limit of Detection

The LoD is confirmed as 12.69 $TCID_{50}$/mL.

Linear Range

In the concentration range of 20.10$TCID_{50}$/mL-2560.26 $TCID_{50}$/mL, the correlation coefficient (r) is not less than 0.990.

Accuracy

Recovery test is used to evaluate the accuracy of the kit. The recovery rate is in the range of 85.0%-115.0%.

Precision

CVs of intra-assay, inter-assay, intra-day, inter-day, different operators and different labs variation studies are not higher than 15%.

Cross-reactivity

The cross-reactivity was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography) in negative samples. Each was tested in triplicate. Results did not show any cross reactivity with the potentially cross-reactive organisms at the concentrations listed below.

Sample No.	Potential Cross-Reactant	Test Concentration	Cross Reactivity (Yes/No)
1	Escherichia coli	1.0×10^{6} CFU/mL	No
2	Hepatitis C Virus (HCV)	1.12×10^{5} pfu/mL	No
3	Hepatitis B Virus (HBV)	1.54×10^{5} pfu/mL	No
4	Influenza B	$0.7\times10^{6.67}$ pfu/mL	No
5	Influenza A	$1.05\times10^{5.67}$ pfu/mL	No
6	Herpes Simplex -1 (HSV-1)	1.12×10^{5} pfu/mL	No
7	Herpes Simplex Virus-2 (HSV-2)	1.47×10^{5} pfu/mL	No
8	Human Immunodeficiency Virus -1 (HIV-1)	2.24×10^{5} pfu/mL	No
9	Enterovirus	2.52×10^{5} pfu/mL	No
10	Staphylococcus epidermidis	1.0×10^{6} CFU/mL	No
11	Legionella pneumophila	3.5×10^{6} CFU/mL	No
12	Chlamydia pneumoniae	1.7×10^{6} CFU/mL	No
13	Mycoplasma pneumoniae	1.5×10^{6} CFU/mL	No
14	Parainfluenza virus	1.26×10^{5} pfu/mL	No
15	Respiratory syncytial virus	1.47×10^{5} pfu/mL	No
16	Adenovirus	1.19×10^{5} pfu/mL	No
17	Cytomegalovirus (CMV)	1.4×10^{5} pfu/mL	No
18	Epstein-Barr Virus (EBV)	1.33×10^{5} pfu/mL	No
19	Varicella Zoster Virus (VZV)	1.05×10^{5} pfu/mL	No
20	Parvovirus B19	1.05×10^{5} pfu/mL	No
21	Streptococcus pneumoniae	1.0×10^{6} CFU/mL	No
22	Streptococcus pyogenes	1.6×10^{6} CFU/mL	No

23	Staphylococcus aureus	1.2×10^6 CFU/mL	No
24	Human coronavirus 229E	1.26×10^5 pfu/mL	No
25	Human coronavirus OC43	1.05×10^5 pfu/mL	No
26	Human coronavirus (NL63)	1.47×10^5 pfu/mL	No

Microbial Interference Studies

Potential microbial interference was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially interfere with SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography) in 3x LoD samples. Each was tested in triplicate. Results did not show any interference with the microbial substances at the concentrations listed below.

Sample No.	Microbial Substance	Test Concentration	Interference (Yes/No)
1	Escherichia coli	1.0×10^6 CFU/mL	No
2	Hepatitis C Virus (HCV)	1.12×10^5 pfu/mL	No
3	Hepatitis B Virus (HBV)	1.54×10^5 pfu/mL	No
4	Influenza B	$0.7\times10^{6.67}$ pfu/mL	No
5	Influenza A	$1.05\times10^{5.67}$ pfu/mL	No
6	Herpes Simplex Virus-1 (HSV-1)	1.12×10^5 pfu/mL	No
7	Herpes Simplex Virus-2 (HSV-2)	1.47×10^5 pfu/mL	No
8	Human Immunodeficiency Virus – 1 (HIV-1)	2.24×10^5 pfu/mL	No
9	Enterovirus	2.52×10^5 pfu/mL	No
10	Staphylococcus epidermidis	1.0×10^6 CFU/mL	No
11	Legionella pneumophila	3.5×10^6 CFU/mL	No
12	Chlamydia pneumoniae	1.7×10^6 CFU/mL	No
13	Mycoplasma pneumoniae	1.5×10^6 CFU/mL	No
14	Parainfluenza virus	1.26×10^5 pfu/mL	No
15	Respiratory syncytial virus	1.47×10^5 pfu/mL	No
16	Adenovirus	1.19×10^5 pfu/mL	No
17	Cytomegalovirus (CMV)	1.4×10^5 pfu/mL	No
18	Epstein-Barr Virus (EBV)	1.33×10^5 pfu/mL	No
19	Varicella Zoster Virus (VZV)	1.05×10^5 pfu/mL	No
20	Parvovirus B19	1.05×10^5 pfu/mL	No
21	Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
22	Streptococcus pyogenes	1.6×10^6 CFU/mL	No
23	Staphylococcus aureus	1.2×10^6 CFU/mL	No
24	Human coronavirus 229E	1.26×10^5 pfu/mL	No
25	Human coronavirus OC43	1.05×10^5 pfu/mL	No

26	Human coronavirus (NL63)	1.47×10^5 pfu/mL	No

Endogenous Interference

Endogenous Interference of SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography) was evaluated by testing a panel of potentially interfering substances in negative and 3xLoD samples. Each was tested in triplicate. The endogenous interference substances listed below did not interfere with the test results of the SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography).

Interfering Substance	**Concentration**	**Endogenous Interference (Yes/No)**
Whole Blood	4%	No
Menthol	1.5 mg/mL	No
Naso GEL (NeilMed)	5% v/v	No
CVS Nasal Drops (Phenylephrine)	15% v/v	No
Afrin (Oxymetazoline)	15% v/v	No
CVS Nasal Spray (Cromolyn)	15% v/v	No
Zicam	5% v/v	No
Sore Throat Phenol Spray	15% v/v	No
Tobramycin	4 μg/mL	No
Fluticasone Propionate	5% v/v	No
Mucin	2% w/v	No
Homeopathic (Alkalol)	10% v/v	No
Mupirocin	10 mg/mL	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No

High-dose Hook Effect

No high-dose hook effect was observed when tested with up to a concentration of 2.0 x 10^6 TCID50/mL of heat inactivated SARS-CoV-2 virus with the SARS-CoV-2 Antigen Rapid Test Kit.

Clinical Evaluation

The sensitivity of the test using swab samples was determined with 139 PCR confirmed positive swab samples. The specificity was determined with 250 PCR confirmed negative swab samples. The sensitivity and specificity of the test was compared to a commercial PCR test. A sensitivity of 97.12% and a specificity of 99.60% were determined for the SARS-CoV-2 Antigen Rapid Test Kit.

		PCR results	
		Positive	Negative
SARS-CoV-2 Antigen RAPID TEST Kit	Positive	135	1
	Negative	4	249
	Total	139	250
Sensitivity		97.12% (95CI:92.80%-99.21%)	
Specificity		99.60% (95CI: 97.79%-99.99%)	

14. PROCEDURAL NOTES

14.1. Read the Instructions for Use carefully before performing the test.

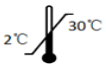
14.2. Testing needs to be performed under proper testing conditions.

14.3. Protect the test cassette from moisture.

14.4. All reagents and samples should reach room temperature before use.

14.5. Do not use turbid or contaminated samples.

15. EXPLANATION OF THE SYMBOLS USED

IVD	In vitro diagnostic medical device
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use-by date
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2 ℃~30 ℃.
	Contents sufficient for 25 tests.
	Do not re-use
	Caution
	Keep dry

16. GENERAL INFORMATION

Manufacturer

Name: Biohit Healthcare (Hefei) Co., Ltd.

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Tel.: +86-551-65652770

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Authorized representative in the European Union

Name: Brand-New Trading GmbH

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17. DATE OF ISSUE

SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography) insert.

Version 01, June 07, 2021.